

AUG 26 2002



653.1006

**UNITED STATES PATENT AND TRADEMARK OFFICE**

**RECEIVED**

Re: Application of: Donald P. REITBERG

AUG 29 2002

Serial No.: 09/872,815

TECH CENTER 1600/2900

Filed: June 1, 2001

For: **Single-Patient Drug Trials Used With  
Accumulated Database: Flowchart**

#6  
Plunkett  
9/3/02

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

August 22, 2002

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicant hereby makes of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement is filed under 37 C.F.R. § 1.97 (b), before the mailing date of a first Office Action on the merits.

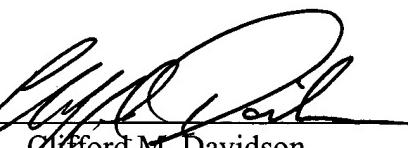
It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record. If any of the publications listed thereon are missing, the Examiner is requested to contact the undersigned so that a copy can be promptly forwarded.

Applicant respectfully submits that the references cited in the accompanying Form PTO-1449 were cited in either the International Search Report or the Written Opinion from corresponding International Application No. PCT/US01/17700. Copies of the International Search Report, Written Opinion and cited references are enclosed for the Examiner's review.

It is believed that no fee is due for this submission. If a fee is deemed to be due, the Commissioner for Patents is hereby authorized to charge said fee to Deposit Account No. 50-0552.

Respectfully submitted,  
DAVIDSON, DAVIDSON & KAPPEL, LLC

By



Clifford M. Davidson  
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AUG 26 2002

Docket No.: 653.1006  
Date: August 22, 2002ASSISTANT COMMISSIONER FOR PATENTS  
Washington, DC 20231

In re application of: Donald P. Reitberg  
 Serial No.: 09/872,815  
 Filed: June 1, 2001  
 For: Single-Patient Drug Trials Used With Accumulated Database: Flowchart

Sir:

Transmitted herewith is a:

- Petition for extension under 37 C.F.R. 1.136 (in duplicate)
- Other: -Information Disclosure Statement  
-PTO-1449 Form with cited references  
-Copy of International Search Report and Written Opinion from PCT/US01/17700

- Check(s) in the amount of \$0.00 is/are attached to cover:
- Filing fee for additional claims under 37 C.F.R. 1.16
- Petition fee for extension under 37 C.F.R. 1.136
- Other:

- The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.

- Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
- Any patent application processing fees under 37 C.F.R. 1.17.
- Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

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I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on August 22, 2002

DAVIDSON, DAVIDSON &amp; KAPPEL, LLC

BY Richard V. Zanglau

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TECH CENTER 1600/2900

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| FORM PTO-1449<br>(REV. 7-80)  |    | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE  |   |   |   |   |   |   | ATTY. DOCKET NO.:<br>653.1006 |                                  | SERIAL NO.: 09/872,815 |          |                            |     |    |
|---|----|---|---|---|---|---|---|---|-------------------------------|----------------------------------|------------------------|----------|----------------------------|-----|----|
| LIST OF PRIOR ART CITED BY APPLICANT<br><br>(Use several sheets if necessary)   |    |   |   |   |   |   |   |   |                               | APPLICANT(S): Donald P. REITBERG |                        |          |                            |     |    |
|   |    |   |   |   |   |   |   |   |                               | FILING DATE:<br>June 1, 2001     |                        | GROUP:   |                            |     |    |
| U.S. PATENT DOCUMENTS   |    |   |   |   |   |   |   |   |                               |                                  |                        |          |                            |     |    |
| *EXAMINER INITIAL   |    | DOCUMENT NUMBER   |   |   |   |   |   |   | DATE                          | NAME                             | CLASS                  | SUBCLASS | FILING DATE IF APPROPRIATE |     |    |
| AA  |    | 6   | 0 | 2 | 9 | 1 | 3 | 8 | 02/22/00                      | Khorasani et al.                 | 705                    | 2        | 08/15/97                   |     |    |
| AB  |    | 5   | 9 | 9 | 1 | 7 | 3 | 1 | 11/23/99                      | Colon et al.                     | 705                    | 3        | 02/01/99                   |     |    |
| AC  |    | 5   | 5 | 9 | 4 | 6 | 3 | 7 | 01/14/97                      | Eisenberg et al.                 | 395                    | 202      | 05/26/93                   |     |    |
| AD  |    |   |   |   |   |   |   |   |                               |                                  |                        |          | RECEIVED                   |     |    |
| AE  |    |   |   |   |   |   |   |   |                               |                                  |                        |          | AUG 29 2002                |     |    |
| AF  |    |   |   |   |   |   |   |   |                               |                                  |                        |          |                            |     |    |
| AG  |    |   |   |   |   |   |   |   |                               |                                  |                        |          | TECH CENTER 1600/2900      |     |    |
| FOREIGN PATENT DOCUMENTS  |    |   |   |   |   |   |   |   |                               |                                  |                        |          |                            |     |    |
|   |    | DOCUMENT NUMBER   |   |   |   |   |   |   | DATE                          | COUNTRY                          | CLASS                  | SUBCLASS | TRANSLATION                |     |    |
|   |    |   |   |   |   |   |   |   |                               |                                  |                        |          |                            | YES | NO |
| AH  |    | 9   | 8 | 1 | 2 | 6 | 6 | 9 | 03/26/98                      | WO                               |                        |          |                            |     |    |
| AI  |    | 1   | 0 | 2 | 1 | 4 | 2 | 9 | 08/11/98                      | Japan                            |                        |          |                            | X   |    |
| AJ  |    |   |   |   |   |   |   |   |                               |                                  |                        |          |                            |     |    |
| AK  |    |   |   |   |   |   |   |   |                               |                                  |                        |          |                            |     |    |
| AL  |    |   |   |   |   |   |   |   |                               |                                  |                        |          |                            |     |    |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)  |    |   |   |   |   |   |   |   |                               |                                  |                        |          |                            |     |    |
|   | AM | WEINHOLD, L.L. et al., "A Meta-analytic Model for Integrating Outcomes in Drug Research: Subjective Effects of Phenylpropanolamine Related to Abuse Potential," Journal of Clinical Research and Drug Development. 1994 Vol.8. pages 57-71. |   |   |   |   |   |   |                               |                                  |                        |          |                            |     |    |
|   | AN | SACHIDANANDAM, R. et al., "A map of human genome sequence variation containing 1.42 million single nucleotide polymorphisms," Nature. 15 February 2001, Vol. 409, pages 928-933.  |   |   |   |   |   |   |                               |                                  |                        |          |                            |     |    |
|   | AO | LARSON, E.B. et al., "Randomized Clinical trials in Single Patients During a 2-Year Period," Journal of the American Medical Association. 08 December 1993, Vol. 270, No. 22, pages 2708-2712.  |   |   |   |   |   |   |                               |                                  |                        |          |                            |     |    |
|   | AP | EVANS, W.E. et al., "Pharmacogenomics: Translating Functional Genomics into Rational Therapeutics," Science. 15 October 1999, Vol. 286, pages 487-491.  |   |   |   |   |   |   |                               |                                  |                        |          |                            |     |    |
|   | AQ | Abstract of JP 1021429 (English)  |   |   |   |   |   |   |                               |                                  |                        |          |                            |     |    |
|   | AR |   |   |   |   |   |   |   |                               |                                  |                        |          |                            |     |    |
| EXAMINER  |    |   |   |   |   |   |   |   |                               | DATE CONSIDERED                  |                        |          |                            |     |    |
| *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |    |   |   |   |   |   |   |   |                               |                                  |                        |          |                            |     |    |